# Complete Summary

#### **GUIDELINE TITLE**

Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for neck pain.

#### BIBLIOGRAPHIC SOURCE(S)

Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for neck pain. Phys Ther 2001 Oct; 81(10): 1701-17. [85 references] PubMed

# **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

SCOPE

**DISCLAIMER** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES** IDENTIFYING INFORMATION AND AVAILABILITY

# **SCOPE**

# DISEASE/CONDITION(S)

Neck pain (acute and chronic)

# **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness Management Rehabilitation Treatment

#### CLINICAL SPECIALTY

Chiropractic Family Practice Internal Medicine Neurology Orthopedic Surgery Physical Medicine and Rehabilitation Rheumatology

#### INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physical Therapists Physician Assistants Physicians

# GUIDELINE OBJECTIVE(S)

- To describe the Philadelphia Panel evidence-based clinical practice guidelines (EBCPGs) of rehabilitation interventions for nonspecific neck pain
- To improve appropriate use of rehabilitation interventions for neck pain

#### TARGET POPULATION

Individuals with acute or chronic neck pain

# INTERVENTIONS AND PRACTICES CONSIDERED

1. Therapeutic exercises for chronic neck pain

Note: Guideline developers considered but did not specifically recommend the following interventions:

- Therapeutic exercises for acute neck pain
- Mechanical traction
- Massage
- Thermal therapy (hot or cold packs)
- Electrical stimulation
- Electromyographic (EMG) biofeedback
- Transcutaneous electrical nerve stimulation (TENS)
- Therapeutic ultrasound
- Combinations of rehabilitation interventions

#### MAJOR OUTCOMES CONSIDERED

- Functional status
- Pain
- Ability to work
- Patient global improvement
- Patient satisfaction
- Quality of life

### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

# Identifying and Assessing the Evidence

To answer the clinical questions, systematic reviews were performed for all rehabilitation interventions of interest and the 4 clinical conditions, according to the methods of The Cochrane Collaboration. Before reviews were conducted de novo, the Cochrane Database of Systematic Reviews was searched for existing Cochrane reviews of the interventions and conditions of interest. Several existing Cochrane reviews addressed the interventions and clinical conditions of interest, but did not answer the clinical questions because those reviews looked at different interventions, were restricted to double-blind trials, excluded relevant studies, or used different outcomes and analytic techniques.

# Identifying the Evidence

A literature search was conducted according to the Cochrane methodology for the identification of randomized controlled trials (RCTs), modified to identify controlled clinical trials, cohort studies, and case-control studies. The electronic search strategy was designed based on the defined clinical questions specifying the populations, interventions, outcomes, and study designs that were of interest. Electronic searches were conducted up to July 1, 2000, in MEDLINE from 1962, EMBASE from 1988, CINAHL from 1982, the Cochrane Controlled Trials Register, HEALTHSTAR from 1975, the database of the Cochrane Field of Rehabilitation and Related Therapies (based in Denmark), and PEDro (Physiotherapy Evidence Database 2000 update). Reference lists of included studies and other meta-analyses were hand-searched for relevant articles. The members of the Philadelphia Panel (experts from rheumatology, orthopedic surgery, neurology, physical therapy, physiatry, back pain and internal medicine, and family medicine) were asked whether any additional studies had been missed.

# Assessing the Evidence

The relevance of studies retrieved using electronic searching was assessed by 2 independent reviewers who screened the titles and abstracts, using the predetermined checklist of selection criteria. The systematic reviews were restricted to articles published in English, French, or Spanish. Any article identified by one reviewer as potentially relevant was retrieved for closer review. Upon retrieval of the full article, 2 independent reviewers determined relevance to the clinical questions.

#### NUMBER OF SOURCE DOCUMENTS

Number of articles initially identified: 3,476

Number of articles considered potentially relevant based on selection criteria: 203

Number of articles included in final selection: 8

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

#### Grades of Evidence

- I: Evidence from at least 1 properly randomized controlled trial (RCT)
- II-1: Evidence from well-designed controlled trials without randomization
- II-2: Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 center or research group
- II-3: Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

#### METHODS USED TO ANALYZE THE EVI DENCE

Meta-Analysis Review of Published Meta-Analyses Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

## Summarizing the Evidence

Data were extracted by 2 independent reviewers from the included studies, using predetermined paper-based forms. These forms collected data regarding the benefits and harms of the intervention as well as population characteristics, trial design, allocation concealment, and details of the interventions. These reviewers also assessed methodological quality of randomization, double-blinding, and description of withdrawals and dropouts using a validated scale. Differences in data extraction or quality assessment were resolved by consultation with a third reviewer.

#### Synthesizing the Evidence

The number of included studies was presented graphically in a 3-axis "cityscape", where each clinical condition was represented by a "street" of rehabilitation interventions, the height of which represented the number of studies identified for that clinical condition and intervention. This schematic was used to prioritize the analysis of data.

#### Clinical Relevance

The results were presented in tables with 2 shaded columns showing the absolute benefit and the relative difference in the change from baseline. Absolute benefit was calculated as the improvement in the treatment group less the improvement in the control group, in the original units. Relative difference in the change from baseline was calculated as the absolute benefit divided by the baseline mean (weighted for the treatment and control groups). The relative difference in change was used to provide clinically meaningful information about expected improvement relative to the placebo or untreated group with each intervention. For this analysis, results from individual trials were not combined statistically. Rather, results from individual trials were presented in a table, allowing the comparison of the percentage of improvement in each trial.

# Statistical Significance

Meta-analysis was used to analyze the difference between treatment and control groups at the end of study. For continuous outcomes, results were analyzed as weighted mean differences, where the weighting factor was determined by the inverse of the variance. Where the same concept was measured with different scales (e.g., pain), standardized mean differences were used to combine end-of-study results. For dichotomous outcomes, relative risks were calculated. Heterogeneity was tested with Cochrane's Q test. Fixed-effects models were used throughout, unless heterogeneity was significant (P<.05), in which case random effects models were considered.

The pooled results were presented in a graphical format, using the Review Manager (RevMan) computer program, Version 4.1 for Windows,\* showing the point estimate (difference between treatment and control groups) and the 95% confidence intervals for each trial and for the pooled estimate.

\* Oxford, England: The Cochrane Collaboration, 2000

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Translating Evidence into a Clinical Practice Guideline

The results of the evidence synthesis were sent to the Philadelphia Panel for their review. A 1-day panel face-to-face meeting was used to determine how to

incorporate opinion into the interpretation of results as well as how to apply this methodology.

# Using and Gathering Opinion

At the panel meeting, 4 hours were spent on defining a transparent and reproducible method of assessing the evidence synthesis and making recommendations, with the consensus of all panelists.

#### Outcomes

The panel reviewed the relevance of key outcomes for deciding whether a given intervention has clinical benefit. The panel decided to take the clinician and patient perspective rather than a payer perspective. The following outcomes were agreed upon as having clinical importance:

- 1. Pain
- 2. Function/Quality of life (QOL)
- 3. Return to work
- 4. Patient global assessment (patient's assessment of overall disease activity or improvement)
- 5. Patient satisfaction

The panel believed that scales demonstrated to be valid and responsive to change should be required to support a positive recommendation (A or B). Other outcomes, although providing useful information in studies, were believed to be insufficient to warrant a grade A or B recommendation.

## Clinical Importance and Statistical Significance

There is some empirical evidence in rheumatology that greater than 20% improvement is viewed by patients as a clinically important difference between 2 interventions and that this discriminates active from placebo/control in all the randomized controlled trials (RCTs) reviewed for the American College of Rheumatology (ACR) The American College of Rheumatology criterion of 20% improvement was developed in 3 steps: (1) a survey of rheumatologists using patient scenarios to identify the cutoff that corresponds best with rheumatologists' impression of improvement, (2) testing, in existing data sets, which cutoff criteria maximally discriminated effective from placebo and minimized the placebo response, and (3) testing of the 8 remaining cutoff definitions for ease of use and best accordance with clinician impression of improvement.

A difference of 2 points on the Roland scale (0-24 scale) is widely used as a minimally important change for back pain, and this amounts to approximately 15% improvement relative to the control group (when considering the usual baseline Roland scale score of 11 or 12).

The panel decided to accept 15% difference between groups as clinically important and that a 15% or greater difference and statistical significance were required for grade A and B recommendations. The panel decided that a C+

recommendation could be used to demonstrate that a potential clinically important benefit of 15% or greater was found but without statistical significance.

# Defined Diagnosis and Reproducible Study Population

For any recommendation, the panel decided that the diagnosis and population must be described in sufficient detail to be of use clinically. Furthermore, the panel decided that studies that combined clinically heterogeneous populations should be excluded (e.g., patients with acute and chronic low back pain in the same trial).

# Study Design and Methodologic Quality

The panel decided that evidence from one or more randomized controlled trials of a clinically important benefit ( $\geq$ 15%) that is statistically significant was necessary for a grade A recommendation. A grade B recommendation would be given for a clinically important benefit ( $\geq$ 15%) that is statistically significant if the evidence was from observational studies or controlled clinical trials. Because there is less confidence in the results from nonrandomized trials, controlled clinical trials were accepted only if they scored 3 or more out of 5 on the Jadad scale, which gives 2 points for randomization, 2 points for blinding, and 1 point for describing withdrawals. Evidence of clinical importance ( $\geq$ 15%) but not statistical significance would be considered a grade C+ recommendation. Based on these decisions, grade C recommendations would be given to those interventions where an appropriate outcome was measured in a study that met the inclusion criteria and no clinical importance was shown.

No recommendation was possible when the data were insufficient, and these evidence-based clinical practice guidelines (EBCPGs) were assigned a classification of "Insufficient Data" (ID). This classification was used because there were (1) interventions where no relevant outcome using a validated scale was reported, (2) studies with  $\leq$ 10 patients randomly assigned to the trial, and (3) interventions where only head-to-head trials were available.

### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

#### Grades of Recommendations

	Clinical Importance	Statistical Significance	Study Design
Grade A	>15%	p<0.05	Randomized controlled trial (RCT) (single or meta-analysis)
Grade B	>15%	p<0.05	Controlled clinical trial (CCT) or observational (single or meta-analysis), with a quality score of 3 or more on the 5-point Jadad methodologic quality checklist
Grade C+	>15%	Not significant	RCT or CCT or observational (single or meta-analysis)
Grade C	<15%	Unimportant*	Any study design
Grade			Well-designed RCT with >100 patients

	Clinical	Statistical	Study Design
	Importance	Significance	
D			

<sup>\*</sup> For grade C, statistical significance is unimportant (i.e., clinical importance is not met; therefore, statistical significance is irrelevant).

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups External Peer Review Internal Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

External review by practitioners and incorporation of their comments into the evidence-based clinical practice guidelines (EBCPGs) are important to ensure the uptake and relevance of guidelines. The guidelines were sent to the Philadelphia Panel for review. In order to judge the clinical usefulness, the positive recommendations were sent to 324 practitioners for their feedback. Practitioners were selected from membership lists of key professional associations, including physical therapists, orthopedic surgeons, physiatrists, back specialists, family practitioners, and rheumatologists. Practitioners were asked 3 questions for each guideline. This feedback was then discussed by the panel, and the guidelines were revised accordingly. In this way, the feedback from the practitioners was incorporated into the completed evidence-based clinical practice guidelines.

Comparison with Guidelines for Other Groups

Guidelines from the following groups were discussed: Quebec Task Force and the British Medical Journal Publishing Group.

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

The evidence grades (I-III) and recommendation grades (A-C) are defined at the end of the "Major Recommendations" field.

#### Acute Neck Pain (<4 weeks)

Intervention: Mechanical Traction for Acute Neck Pain (<4 Weeks) Level II (controlled clinical trial [CCT]) Grade ID (Insufficient Data) Recommendation: The Philadelphia Panel recommended that there is insufficient evidence to include or exclude (ID) mechanical traction alone as an intervention for acute nonspecific neck pain.

Intervention: Transcutaneous electrical nerve stimulation (TENS) for Acute Neck Pain (<4 Weeks)
Level I (randomized controlled trial [RCT])
Grade C for Pain (No Benefit Demonstrated)

Clinical Recommendation in Comparison With Other Guidelines: The Philadelphia Panel recommends that there is poor evidence to include or exclude TENS alone (grade C for pain) as an intervention for acute neck pain.

Interventions for Acute Neck Pain with Insufficient Evidence

No evidence from controlled trials or cohort studies was found for electromyographic (EMG) biofeedback, thermotherapy, massage, electrical stimulation, therapeutic exercises, or combined interventions for acute neck pain.

For therapeutic exercises, one RCT of manual therapy combined with exercises was excluded because manual therapy was not given to the control group. Another RCT, which compared continuing normal activities with neck collar and time off work, was excluded because of lack of an appropriate control group (i.e., the effects of neck collar and sick leave could not be separated).

For combined interventions, one RCT of combined rehabilitation interventions was excluded because manual therapy was given to the treatment group but not to the control group.

# Chronic Neck Pain (>12 WEEKS)

Intervention: Therapeutic Exercises for Chronic Neck Pain (>12 Weeks) Level I (RCT)

Grade A for Pain and Function, Grade B for Patient Global Assessment (Clinically Important Benefit)

Clinical Recommendation in Comparison With Other Guidelines: The Philadelphia Panel recommends that there is good evidence to include supervised exercise programs alone (including proprioceptive and traditional exercises) for the management of chronic (>12 weeks) neck pain (grade A for pain and function, grade B for patient global assessment).

Intervention: Mechanical Traction for Chronic Neck Pain (>12 Weeks) Level II (CCT) Insufficient Data (ID)

Clinical Recommendation in Comparison With Other Guidelines: There are insufficient data to make a recommendation regarding mechanical traction alone in chronic neck pain.

Intervention: Therapeutic Ultrasound for Chronic Neck Pain (>12 Weeks) Level II

Grade C for Pain (No Evidence of Benefit)

Clinical Recommendation in Comparison With Other Guidelines: The Philadelphia Panel recommends that there is poor evidence to include or exclude therapeutic ultrasound alone (grade C for pain) as an intervention for chronic neck pain.

Interventions for Chronic Neck Pain with Insufficient Data

Interventions that could not be assessed due to lack of controlled studies were EMG biofeedback, massage, thermotherapy, electrical stimulation, TENS, and combined rehabilitation interventions. For combined interventions, one RCT was excluded because manual therapy was included in the "physiotherapy" group, but not the control group.

#### **Definitions**:

#### Grades of Recommendations

	Clinical Importance	Statistical Significance	Study Design
Grade A	>15%	p<0.05	Randomized controlled trial (RCT) (single or meta-analysis)
Grade B	>15%	p<0.05	Controlled clinical trial (CCT) or observational (single or meta-analysis), with a quality score of 3 or more on the 5-point Jadad methodologic quality checklist
Grade C+	>15%	Not significant	RCT or CCT or observational (single or meta-analysis)
Grade C	<15%	Unimportant*	Any study design
Grade D			Well-designed RCT with >100 patients

<sup>\*</sup> For grade C, statistical significance is unimportant (i.e., clinical importance is not met; therefore, statistical significance is irrelevant).

## Grades of Evidence

- I: Evidence from at least 1 properly randomized controlled trial (RCT)
- II-1: Evidence from well-designed controlled trials without randomization
- II-2: Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 center or research group
- II-3: Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

CLINICAL ALGORITHM(S)

None provided

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is specifically stated for each recommendation (see 'Major Recommendations' field).

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

- Appropriate use of rehabilitation interventions for neck pain.
- The Panel's meta-analysis showed that proprioceptive and traditional therapeutic exercises are effective for pain relief in chronic cervical pain.

POTENTIAL HARMS

Not stated

# IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

# IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for neck pain. Phys Ther 2001 Oct;81(10):1701-17. [85 references] PubMed

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Oct

GUI DELI NE DEVELOPER(S)

Philadelphia Panel - Independent Expert Panel

SOURCE(S) OF FUNDING

This study was financially supported by an unrestricted educational grant from the Cigna Foundation, Philadelphia, Pa, USA; the Ministry of Human Resources and Development, Government of Canada (Summer Students Program); and the Ontario Ministry of Health and Long-Term Care (Canada).

**GUI DELI NE COMMITTEE** 

Philadelphia Panel

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Clinical Specialty Experts: John Albright, MD (Orthopaedic Surgeon), American Academy of Orthopaedic Surgeons, USA; Richard Allman, MD (Internist, Rheumatologist), American College of Physicians, USA; Richard Paul Bonfiglio, MD (Physiatrist); Alicia Conill, MD (Internist), University of Pennsylvania, Philadelphia, Pa, USA; Bruce Dobkin, MD (Neurologist), American Academy of Neurology, USA; Andrew A Guccione, PT, PhD (Physical Therapist), American Physical Therapy Association, USA; Scott M Hasson, PT, EdD (Physical Therapist), American College of Rheumatology, Association of Health Professionals, USA; Randolph Russo, MD (Physiatrist), American Academy of Physical Medicine and Rehabilitation, USA; Paul Shekelle, MD, PhD (Internist), Cochrane Back Group; Jeffrey L Susman, MD (Family Practice), American Academy of Family Physicians, USA

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#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

### **GUIDELINE STATUS**

This is the current release of the guideline.

#### GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from Peter Tugwell, MD, MSc, Chair, Centre for Global Health, Institute of Population Health, 1 Stewart St, Rm 312, Ottawa, Ontario, Canada K1N 6N5 (<a href="mailto:ptugwell@uottawa.ca">ptugwell@uottawa.ca</a>).

#### AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions: overview and methodology. Phys Ther 2001 Oct; 81(10):1629-1640.

Print copies: Available from Peter Tugwell, MD, MSc, Chair, Centre for Global Health, Institute of Population Health, 1 Stewart St, Rm 312, Ottawa, Ontario, Canada K1N 6N5 (ptugwell@uottawa.ca).

#### PATIENT RESOURCES

None available

#### NGC STATUS

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